DATA EVALUATION RECORD

SUCROSE
(Bull Run Fly Attractant)

STUDY TYPE: Waiver Requests for Mammalian Toxicity Testing Requirements

MRID 47396927

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Prepared by
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Task Order No. 08-031

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Disclaimer

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EPA Secondary Reviewer:	
STUDY TYPE:	Waiver Requests for Mammalian Toxicity Testing Requirements
MRID NO:	47396927
DECISION NO:	392213
DP BARCODE:	DP353134
TEST MATERIAL:	Indole
PROJECT STUDY NO:	Not applicable
SPONSOR:	Bull Run Scientific, VBT, 7400 Beaufont Springs Drive, Suite 300, Richmond, VA 23225-5519
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Sucrose: Tier 1 Mammalian Toxicology
AUTHOR:	Smith, C.A.
STUDY COMPLETED:	April 2, 2008
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The study is descriptive in nature, and not subject to the requirements of 40 CFR Part 160.
CONCLUSION:	The information provided is sufficient to grant the requested waivers for the requirements of Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation, Acute Dermal Irritation, Dermal Sensitization, Hypersensitivity Incidents, and Prenatal Development for sucrose. Additional justification is needed for waivers of Bacterial Reverse Mutation Assay, *In vitro* Mammalian Cell Assay, and *In vitro* Mammalian Chromosome Aberration testing.

Test Material

Sucrose (present at 42.1% w/w in Bull Run Fly Attractant)

Product Description

Bull Run Fly Attractant is an end use product to be used as an attractant for "filth flies" such as house flies, blow flies, bottle flies, lesser house flies, cluster flies, lance flies, secondary screwworm flies, flesh flies, and false stable flies. The product is composed of a fly attractant mix (97.3% w/w) in a [redacted]
Sucrose is present in the product at a concentration of 42.1%. The pouch of attractant is contained in a disposable or reusable trap that is filled with the appropriate amount of water and hung in the treatment area.

Waiver Request

The registrant is requesting waivers for the following requirements:

Acute Oral Toxicity	(OPPTS 870.1100)
Acute Dermal Toxicity	(OPPTS 870.1200)
Acute Inhalation Toxicity	(OPPTS 870.1300)
Acute Eye Irritation	(OPPTS 870.2400)
Acute Dermal Irritation	(OPPTS 870.2500)
Dermal Sensitization	(OPPTS 870.2600)
Hypersensitivity Incidents	(OPPTS 885.3400)
Prenatal Development	(OPPTS 870.3700)
Bacterial Reverse Mutation Assay	(OPPTS 870.5100)
In vitro Mammalian Cell Assay	(OPPTS 870.5300)
In vitro Mammalian Chromosome Aberration	(OPPTS 870.5375)

Registrant's Justification

Sucrose occurs naturally in sugar cane, sugar beets, sweet sorghum, and sugar maples.

Bull Run Fly Attractant is packaged in unit doses. The largest proposed net weight for the attractant is 69.97 g. The attractant nominally contains 42.8% sucrose (MRID 47396927 incorrectly states 40.8%), making the sucrose content 29.9 g. The density of sucrose is 1.587 g/cm^3. Thus, the largest proposed package size of the product would contain 1.3 tablespoons of sucrose (MRID 47396927 incorrectly states 1.2 tablespoons):

(29.9 g) x (1 cm^3/1.587 g) x (1 tablespoon/15 cm^3) = 1.3 tablespoons.

Acute Oral Toxicity

ChemIDplus Lite gives the acute oral LD_{50} for sucrose in rats as 29,700 mg/kg.

Acute Dermal Toxicity

Sucrose is the same as white table sugar. The general public has routine dermal contact with sucrose, e.g., kneading of bread dough, without adverse effects. Bull Run Fly Attractant is packaged in a water soluble pouch, and no significant dermal exposure to sucrose is anticipated from handling the pouch.

Acute Inhalation Toxicity

The vapor pressure of sucrose is estimated to be 3.53 x 10^{-16} mm Hg at 25°C (MPBWIN v 1.42). No significant exposure to sucrose vapor is expected. Use directions for Bull Run Fly Attractant do not include spraying the attractant. Therefore, no significant inhalation exposure is anticipated.

Acute Eye Irritation

No significant ocular exposure to sucrose associated with the use of Bull Run Fly Attractant is anticipated. The attractant is packaged in a water-soluble pouch that is not to be opened by the user. The trap opening into which the water is added to dissolve the pouch containing the attractant is small in proportion to the overall trap size. Since the attractant suspension is not sprayed, there will be no spray drift into the user's eyes. During manufacture of the product, workers are protected by engineering controls and the appropriate PPE.

Acute Dermal Irritation/Dermal Sensitization

No significant dermal exposure to sucrose associated with the use of Bull Run Fly Attractant is anticipated. The attractant is packaged in a water-soluble pouch that is not to be opened by the user. The trap opening into which the water is added to dissolve the pouch containing the attractant is small in proportion to the overall trap size. Since the attractant suspension is not sprayed, there will be no spray drift onto the user's skin or clothing. During manufacture of the product, workers are protected by engineering controls and the appropriate PPE.

Hypersensitivity Incidents

The registrant is not aware of any hypersensitivity incidents associated with sucrose. Should the registrant become aware of hypersensitivity incidents, they will be reported to the Agency.

Prenatal Development

No significant oral, dermal, or inhalation exposure to sucrose is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirement for prenatal development should be waived.

Bacterial Reverse Mutation Assay

No significant oral, dermal, or inhalation exposure to sucrose is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirement for a bacterial reverse mutation assay should be waived.

In vitro Mammalian Cell Assay/*In vitro* Mammalian Chromosome Aberration

No significant oral, dermal, or inhalation exposure to sucrose is anticipated from the use of Bull Run Fly Attractant. Therefore, the requirements for an *in vitro* mammalian cell assay and an *in vitro* mammalian chromosome aberration assay should be waived.

Reviewer's Comments

The reviewer believes that sufficient information was provided to grant the requested waivers for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation, Acute Dermal Irritation, Dermal Sensitization, Hypersensitivity Incidents, and Prenatal Development. Additional justification (e.g., long history of safe use) is needed for waivers of Bacterial Reverse Mutation Assay, *In vitro* Mammalian Cell Assay, and *In vitro* Mammalian Chromosome Aberration testing.

Pages 5-10*Claimed confidential by submitter*